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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,413	DOMB ET AL.	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12,14-26 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-12, 14-26, and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 17, 2004 has been entered.

Acknowledgment is made of newly added Claim 38.

Claims 1-4, 6-12, 14-26, and 38 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-12, 14-26 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Insertion of the limitation "wherein the agent is present in a homeopathtic amount, which is less than a therapeutically effective amount" in Claim 38 is deemed new matter. In an attempt to

assert that the aforementioned limitation is not new matter, Applicant directs the Office to page 35, example 8 to indicate that the newly inserted limitation is not new matter. However, Applicant's apparent argument is not persuasive because nowhere in the present specification does Applicant expressly describe or define a homeopathic amount of an agent as less than a therapeutically effective amount by either expressed definition or by example.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-12, 14-26 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are rendered uncertain by the phrase "which is less than a therapeutically effective amount" because it is unclear as to what is the subject matter of "therapeutically effect amount". The lack of clarity renders the claim vague and ambiguous.

Claim 6 recites the limitation "wherein the herbal active agent or homeopathic agent" in lines 1-2. There is a lack of insufficient antecedent basis for this limitation in the claim, that is [the . . . homeopathic agent].

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6-8, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Green (V).

Applicant claims a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising (a) a bioactive amount of at least one herbal agent selected from the group consisting of herbs, herb extracts, tinctures, essential oils, an mixtures thereof; or an agent selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof, wherein the agent is present in a homeopathic amount, which is less than a therapeutically amount; and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosal. Applicant further claims the composition of claim 1, wherein the

herbal active agent is selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, antiparasitic agent, and combinations thereof. Applicant further claims the composition of claim 1, wherein the herbal active agent or homeopathic agent is selected from a recited Markush group of claim-designated plants, including Echinacea and Calendula; wherein the herbal active agent is an essential oil selected from a recited Markush group, including lavender oil and tea-tree oil; wherein the solid bioadhesive carrier is selected from the group consisting of a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof; and, wherein the composition of claim 1 further comprises an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and mixtures thereof.

On page 284 bridging page 285, under "Clay Poultice", Green teaches a method of making a clay poultice comprising bentonite clay, water and herbal tinctures comprising diluting a herbal tincture with about half as much water (2 parts tincture to 1 part water) to form a mixture and adding the mixture to bentonite clay to form a paste, wherein the proportions of clay to liquid is a tablespoon of clay to each tablespoon of liquid. Green further teaches adding a few drops of Lavender or Tea Tree essential oil (5 to 10 drops) to the composition and applying the composition in a thickness of at least ¼ inch. Green also teaches a bentonite clay poultice for the mouth, teeth and gums, wherein the method of making the solid, self-bioadhesive composition for topical

application and adhesion to oral mucosal comprises adding water to bentonite-clay (a natural solid bioadhesive carrier) to form a malleable peanut butter consistency, rolling the clay into a cylindrical form, and mixing the clay with finely powdered Echinacea root or Goldenrood root with the clay powder before adding the water or an herbal tincture of Poke root (*Phytolacca Americana*).

The reference anticipates the claimed subject matter.

Claims 1, 4, 7, 15-17, 22-24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Tapolsky et al. (A).

Applicant's claimed invention of Claims 1, 4, 6-8, 22 and 24 was set forth above. Applicant further claims the composition of claim 1, further comprising a non-herbal active agent. Applicant further claims the composition of claim 15, wherein the agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chloroprocaine, tetracaine, bupivacine, and etidocaine; and, wherein the non-herbal agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes. Applicant further claims the composition of claim 22, wherein said polyhydric polymer is selected from a recited Markush group.

Tapolsky teaches a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue comprising a therapeutically effective amount of at

least one homeopathic agent (*e.g.*, thymol which is obtained from thyme oil and eugenol which is obtained from clove oil) and a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 5-95% by weight of the total composition, and wherein the bioadhesive comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose. *See* claims 1, 10 and 11; and Column 6, lines 27-37. In Column 5, lines 31-58, Tapolsky teaches that the bioadhesive composition is in the form of a disk having two layers: an adhesive layer and a non-adhesive backing layer. The adhesive layer comprises a film forming polymer which may be crosslinked (see Column 5, lines 61-67; Column 6; and Column 7, lines 1-12). In Column 5, lines 16-30, Tapolsky teaches that the residence times which may be achieved for the referenced composition include 30 minutes to about 3 or about 4 hours. A preferred residence time for effective drug delivery is about 1 to 2 hours. In Column 7, line 13 bridging Column 8, lines 1-12, examples of pharmaceuticals which may be incorporated into the making of the referenced composition are taught, including inflammatory analgesic agents, steroidal anti-inflammatory agents, antihistamines, local anesthetics, bactericides and disinfectants, vasoconstrictors, hemostatics, chemotherapeutic agents, antibiotics, keratolytics, cauterizing agents, and antiviral drugs. Excipients, such as, plasticizers, flavoring and coloring agents, may also further comprise the composition taught by Tapolsky. *See* Column 8, lines 18-24. In Column 8, lines 25-32, Tapolsky teaches that the thickness of the composition may vary, depending on the thickness of each of the layers. Preferably, the bilayer thickness ranges from 0.05 to 1 mm. In Column 12, lines 66-67, a disk having a ½ inch (12.7 mm) is taught by Tapolsky.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 15-17, 22-24, 26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al. (A).

Applicant's claimed invention of Claims 1, 4, 7, 15-17, 22-24 and 26 was set forth above. Applicant further claims the solid composition of claim 1, wherein the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal for at least 30 minutes; wherein the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissue adherence of at least 1 hour; and, wherein the composition has a surface area ranging from about 0.4 to about 3 cm^2.

The teachings of Tapolsky are set forth above.

Tapolsky does not expressly teach a solid, self-bioadhesive composition comprising the instantly claimed measurements. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the thickness, diameter and surface area of the composition taught by Tapolsky because

Tapolsky teaches the requisite ingredients and amounts of ingredients, the residence times for effective drug delivery, and process steps for making the layers of the referenced composition, which can be used in the making of a disc having varying measurements of thickness and diameter. At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation to modify the measurements of the disc-shaped composition taught by Tapolsky to the instantly claimed measurements because Tapolsky teaches, in Column 8, lines 25-30, "The thickness of each layer may vary from 10 to 90% of the overall thickness of the bilayer device, and preferably varies from 30 to 60%." Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the combinations of the ingredients, the amounts of the ingredients, and the process steps for making the layers of the referenced composition in the making of the claimed composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to select result-effect amounts, degrees of thickness and surface area of the claimed ingredients to provide a composition with the claimed functional effect and claimed physical properties. Hence, it appears that the claimed invention is no more than the routine optimization of result effect variables.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-4, 6-8, 22, 24 and 38 are rejected under 35 U.S.C. 103(a) as obvious over Green (V) in view of Tapolsky et al. (*A).

Applicant's claimed invention was set forth above.

The teachings of Green were set forth above. Green teaches the instantly claimed composition except for wherein the composition is in the form of a disc and wherein the composition has the instantly claimed measurements. However, it would have been obvious to one of ordinary skill in the art to modify the form and to adjust the thickness, diameter and surface area of the composition taught by Green to provide the instantly claimed invention because at the time the invention was made it was known in the art that the instantly claimed physical parameters were useful in the making of a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue, as evidenced by the teachings of Tapolsky. For instance, Tapolsky teaches the requisite ingredients and amounts of ingredients, the residence times for effective drug delivery, and process steps for making the layers of the referenced composition, which can be used in the making of a disc having varying measurements of thickness and diameter. At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation to modify the physical form and the measurements of the composition taught by Green to provide the instantly claimed composition because Tapolsky teaches, in Column 8, lines 25-30, "The thickness of each layer may vary from 10 to 90% of the overall thickness of the bilayer device, and preferably varies from 30 to 60%"; and, Green teaches that the bentonite clay poultice comprising bioactive herbal

agents has a thickness of at least ¼ inch, a residency time of ½ hour to 1 hour when applied to oral mucosal tissue and that the size of the composition can be adjusted to the area of tissue wherein the patient is experiencing pain. Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the combinations of the ingredients, the amounts of the ingredients, and the process steps for making the referenced composition in the making of the claimed composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to select result-effect amounts, degrees of thickness and surface area of the claimed ingredients to provide a composition with the claimed functional effect and claimed physical properties. Hence, it appears that the claimed invention is no more than the routine optimization of result effect variables.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-4, 6-11, 15-17, 19, 22-24, 26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al. (A) in view of Iyer et al. (E) and Friedman et al. (D) with evidence provided by Lawless (U).

Applicant's claimed invention of Claims 1-4, 6-8, 15-17, 22-24, 26 and 38 was set forth above. Applicant further claims the composition of claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations. Applicant further claims the composition of claim 1, wherein the herbal active agent is an essential

oil and the essential oil is a natural or synthetic mixture consisting of limonene and at least one myrcene, a-pinene, b-pinene, and sabinene, wherein at least 60% by weight of the mixture is limonene. Applicant further claims the composition of either claim 1 or 9, wherein the monoterpene with three unsaturations is a citrus oil selected fro the group consisting of lemon oil, pomelo oil, citron oil, and combinations thereof.

The teachings of Tapolsky are set forth above. Tapolsky teaches the claimed invention except for wherein the herbal active agent or homeopathic active agent is at least one selected from the Markush group recited in Claim 6, wherein the herbal active agent is at least one essential oil selected from the Markush group recited in Claim 7, wherein the herbal active agent comprises at least one monoterpene with three unsaturations, wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of and at least one of myrcene, a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene, and wherein said monoterpenes with three unsaturations is of citrus oil selected from the group consisting of lemon, pomelo and citron. However, it would have been obvious to one of ordinary skill in the art at the time the invention was mad to add the instantly claimed ingredients having the claim-designated biochemical properties to the composition taught by Tapolsky to provide the claimed invention because Iyer teaches antimicrobial compositions which can be used in the making or oral compositions and Friedman teaches antifungal compositioms which can be used in the making of oral compositions. Firstly, Iyer teaches antimicrobial compositions comprising at least two antimicrobial agents, agent A and agent B, which exhibit reduce

MIC values relative to the MIC for the agents making up the combination measured alone. For example, in Column 3, lines 11-26, Iyer teaches that agent A and agent B are selected from the group consisting of berberine, cedarwood oil, chloramphenicol, citral, citronella oil, cocamidopropyl dimethylglycine, *Glycyrrhiza glabra* extract, hinokitol, juicy fruit basil oil, juniper berries oil, lemon basil oil, lemon oil, and *Rosmarinus officinalis* oil. The compositions taught by Iyer are useful as therapeutic agents such as in oral hygiene products. Secondly, Friedman teaches a combination of an herbal extract and an essential oil which exerts prolonged antifungal activity on mucosal membranes. The herbal extracts include material selected from the group consisting of Plantago, Hypericum, Echinacea, Baptisia, Calendula, Myrrh, Phytolocca, Salvia, Catechu black, Coneflower, Krameria, Tsuga, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis (beehive material), and Sage; and the essential oils are selected from cinnamon oil, cajeput oil, citronella oil, eucalyptus oil, fennel oil, geranium oil, lavender oil, lemon oil, spearmint oil, myrte oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil (see Column 1, lines 6-10; Column 2, lines 38-59; and claims). In Column 5, lines 9-39, Friedman further teaches that the herbal extracts are in the form of a tincture of botanical materials. In Figures 1 and 2, Friedman shows that the referenced compositions have prolonged activity against *Aspergillus niger* and *Candida albicans*. In Column 4, lines 18-37, Friedman teaches that the compositions can be used to combat fungal infection of mucosal organs and the oral cavity. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a

reasonable expectation of success to add the instantly claimed ingredients having the instantly claimed biochemical properties to the composition taught by Tapolsky to provide the claimed invention because Iyer teaches that the antimicrobial compositions of his invention can be used in the making of therapeutic oral hygiene products for growth control of bacteria, such as *Actinomyces viscosus, Campylobacter rectus, Fusobacterium nucleatum, Porphyromonas gingivalis, Streptococcus mutans* and *Streptococcus mutans* (see Column 3, lines 28-38 and 47-51); and Friedman teaches that the compositions of his invention have strong antibacterial activity and anti-inflammatory activity in addition to its antifungal activity, can be used in the making of oral products, and can be used in the treatment of disease conditions such as *Herpes zoster* and *Herpes simplex* infections, dental ulcers, stomatitis, aphthous ulcers, and abscesses (see Column 4, lines 31-37; Column 8, lines 36-42; Column 9, lines 66-67 to Column 10, lines 1-4; and Column 10, lines 30-51). One of ordinary skill in the art at the time the invention was made would have been further motivated and one would have had a high expectation of success to add the antimicrobial compositions taught by Iyer to the bioadhesive composition taught by Tapolsky to provide the claimed invention because Iyer teaches in Table 14 that the combination of the essential oil of lemon (which comprises 70% limonene, myrcene, pinenes and sabinene, as evidenced by the teaching of Lawless) in combination with an antimicrobial Agent B results in a significant decrease in the MIC value against various microorganisms which cause oral or periodontal disease. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the

making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference.

According, the claimed the invention was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-4, 6-12, 15-17, 19, 22-24, 26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al. (A) in view of Friedman et al. (D) and Shuch et al. (F).

Applicant's claimed invention of Claims 1-4, 6-11, 15-17, 19, 22-24, 26 and 38 was set forth above. Applicant further claims the composition of claim 6, furthering

comprising herb tincture active agents selected from the recited Markush group of Claim 6, and further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, KCL and mixtures thereof.

The teachings of Tapolsky are set forth immediately above. Tapolsky teaches the claimed invention except for comprising herb tincture active agents selected from the recited Markush group of Claim 6, and further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, KCL and mixtures thereof. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the composition taught by the composition taught by Tapolsky to provide the instantly claimed invention Friedman teaches antifungal compositions comprising botanical tinctures which can be used in the making of therapeutic oral compositions and Shuch teaches compositions comprising homeopathic salts and herbal botanicals which can be used in the making of therapeutic oral compositions. Firstly, Friedman teaches a combination of an herbal extract and an essential oil which exerts prolonged antifungal activity on mucosal membranes. The herbal extracts include material selected from the group consisting of Plantago, Hypericum, Echinacea, Baptisia, Calendula, Myrrh, Phytolocca, Salvia, Catechu black, Coneflower, Krameria, Tsuga, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis (beehive material), and Sage; and the essential oils are selected from cinnamon oil, cajeput oil, citronella oil, eucalyptus oil, fennel oil, geranium oil, lavender oil, lemon oil, spearmint oil, myrte oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil (see Column 1, lines 6-10; Column 2, lines 38-59; and claims). In Column 5, lines 9-39,

Friedman further teaches that the herbal extracts are in the form of a tincture of botanical materials. In Figures 1 and 2, Friedman shows that the referenced compositions have prolonged activity against *Aspergillus niger* and *Candida albicans*. In Column 4, lines 18-37, Friedman teaches that the compositions can be used to combat fungal infection of mucosal organs and the oral cavity. Secondly, Shuch teaches a biologically absorbable dental composition comprising Vitamin C to promote healing of the mouth from gum disease and to reduce plaque build-up on the teeth; and coenzyme A-10 (ubiquinone) to enhance gum health. Other active agents comprising the composition taught by Shuch include Vitamin E; herbal extracts, e.g., Propolis, Echinacea, grape seed extracts, cranberry extract, stevia, tangerine oil, and lemon oil; and homeopathic tissue salts comprising potassium chloride and sodium chloride. See Column 2, lines 40-67, Column 3, and Column 4, lines 1-42. The formulation may be in the form of a dental prophylaxis paste (see Column 6, lines 64-67; and Examples 9-13, especially Examples 12 and 13, which comprise homeopathic salts). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the bioactive active agents taught by Friedman and Shuch to the composition taught by Tapolsky to provide the instantly claimed composition because Friedman teaches that the compositions of his invention have strong antibacterial activity and anti-inflammatory action in addition to antifungal activity, which can be used in the making of oral products for use in the treatment of disease conditions such as Herpes zoster and Herpes simplex infections, dental ulcers, stomatitis, aphthous ulcers, and abcesses (*see* Column 4, lines 31-37;

Column 8, lines 36-42; Column 9, line 66 to Colunn 10, line 4; and Column 10, lines 30-51); and, Shuch suggests that compositions comprising herbal ingredients and homeopathics act together to reduce and prevent major chronic diseases of the mouth and can be incorporated into the making of a variety of delivery systems for application to gums and oral mucosa tissue (*see* Column 1, lines 24-53 and Column 8, lines 50-60.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference.

According, the claimed the invention was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Allowable Subject Matter

Claims 14, 20 and 21 would be allowable if rewritten to overcome the rejections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood.

MICHELE FLOOD
PATENT EXAMINER

MCF
January 24, 2005